

**YOUR SECURITY.
CONNECTED**

**Opioid Task Force Findings and Recommendations:
The Imperative for Electronic Prescribing of Controlled
Substances**

**Written Testimony for the Senate Committee on Health
Policy**

**Wendy Reilly, Manager, Government Affairs, HID Global
Chad Grant, Senior Vice President, Grant Consulting Group**

May 17, 2016

INTRODUCTION

HID Global is the world's leading manufacturer of secure and trusted identity credentials. We are headquartered in Austin, Texas, and provide identity solutions, including access control badges, digital identification credentials, government identity credentials, and the ecosystem to authenticate all of these credentials.

For more than 25 years, HID Global has been designing, developing and manufacturing secure credentials and/or their component parts for private businesses and governments around the world, including passports for more than 25 countries, government-issued ID cards, the US permanent resident Green Card, and cybersecurity solutions such as user authentication and digital identity assurance. To ensure that someone is who they claim to be, HID Global has invested millions of dollars in research and development so that our secure identity solutions are the most counterfeit and fraud-resistant solutions available to both public and private sector customers.

Our products enable organizations-both public and private-to effectively manage the risks associated with identity authentication. To provide this level of assurance, these solutions must be interoperable with a variety of platforms and systems.

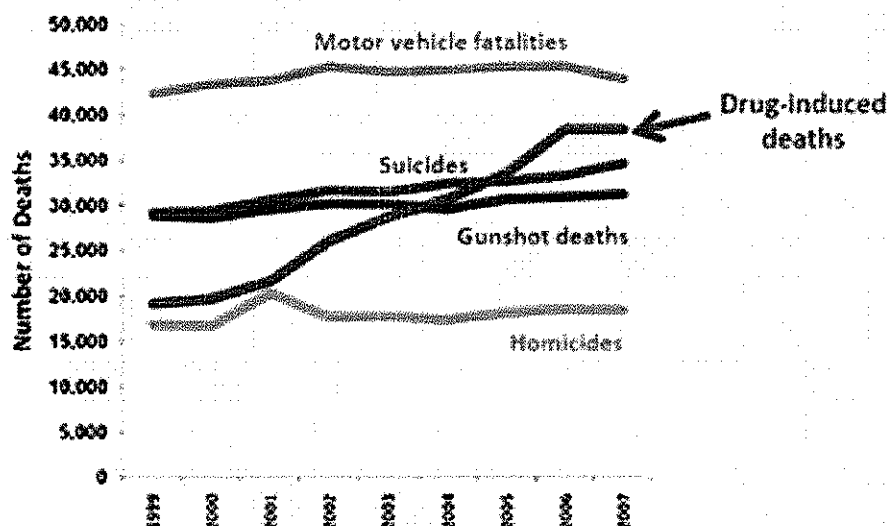
THE CRISIS

America is facing a national public health crisis: prescription drug abuse. This pervasive problem does not discriminate based on gender, socioeconomic status or race; it traverses all the traditional distinctions of many public health crises.

According to a 2011 White House report¹ on drug abuse, prescription drug abuse is the Nation's fastest growing drug problem. In fact, as illustrated in the image below, prescription drug induced deaths ranked second only to motor vehicles fatalities from 2007-2011. And this number is on the rise.

¹ The White House 2011 Prescription Drug Abuse Prevention Plan: [Epidemic: Responding to America's Prescription Drug Abuse Crisis](#)

Drug-Induced Deaths Second Only to Motor Vehicle Fatalities, 1999–2007



Source: National Center for Health Statistics, Centers for Disease Control and Prevention. National Vital Statistics Reports Deaths: Final Data for the years 1999 to 2007 (2001 to 2010).

Controlled substances (Schedules II-IV) account for nearly 12 percent of those prescribed each year. Statistics show that every day, 44 people die as a result of prescription opioid overdose. Deaths from drug overdose continue to sky-rocket requiring an increased focus on compliance and safety when prescribing controlled substances. In 2014, more people died from drug overdose than any previously recorded year. Unfortunately, prescription drug abusers often transition to illegal drugs, such as heroin, because they are less expensive and easier to obtain. 80 percent of heroin abusers began their addiction by using prescribed opioids (most often, OxyContin). Heroin and OxyContin are molecularly almost identical; they operate in the same manner in the body and produce very similar effects. Emergency department visits involving misuse or abuse of prescription opioids increased 153% between 2004 and 2011, and admissions to treatment programs linked to prescription opioids more than quadrupled from 2002-2012.

Additionally, waste and fraud are also prevailing concerns when discussing the prescribing of Schedule II drugs. According to a Department of Health and Human Service, Inspector General Report in 2012², Medicare Part D (prescription drug coverage) erroneously paid out \$25 million billed as refills of Schedule II drugs in 2009. However, Federal law explicitly

² <http://oig.hhs.gov/oei/reports/oei-02-09-00605.pdf>

prohibits the refilling of these drugs. The Inspector General's Report identified this as a red flag because, "in no circumstances is Medicare supposed to pay for refills of these drugs."

As this problem continues to grow, communities are grappling with containing the severe adverse effects. A recent Congressional hearing on January 27, 2016 focused on the prescription drug crisis. During that hearing, Senators whose communities have been ravaged by prescription drug and heroin abuse discussed the need for a more holistic and cooperative approach. Panelists including, members of Congress, US Department of Health and Human Services and the US Drug Enforcement Administration (DEA) discussed the need for doctors, law enforcement, pharmacists, policymakers, and public health officials at all levels of government to partner together to mitigate this growing epidemic. A key component of this partnership includes the private sector and its expertise in creating solutions for this purpose. Specifically, officials are enlisting the help of health IT professionals to use existing technology for the electronic prescribing of controlled substances—EPCS.

The use of electronic prescribing technologies enables providers to track and monitor electronic prescriptions of controlled substances through each state's prescription drug monitoring program (PDMP). Currently, every state except Missouri has a state prescription drug monitoring program. The partnership between providers, pharmacists PDMPs, and the technology community encourages a more accountable system of prescription monitoring through the use of tools such as EPCS. Ultimately, this must be a collaborative effort between states, law enforcement, the medical community and the private sector to successfully combat this escalating problem.

TECHNOLOGY SOLUTION—EPCS

In response to the rising prescription drug abuse problem, the DEA and states have worked together to create programs and craft legislation to deter abuse and misuse. In 2010, the DEA legalized the use of EPCS and established regulations; it is now allowed in all 50 states and mandatory in the state of New York. EPCS regulations require two-factor authentication of prescribers, improving security and providing an audit trail for authorities. Providers who use EPCS will realize a reduction in paperwork; EPCS will also help to reduce the number of prescription errors and paper prescription forgeries. EPCS can also help to create a more positive patient experience since prescriptions are more likely to be filled by the time the patient arrives at their preferred pharmacy. Additionally, EPCS helps both providers and pharmacies to integrate and manage prescriptions into other records. Ultimately, this leads to increased efficiency while also reducing overall costs. While EPCS is not the panacea to solve the prescription drug abuse epidemic, it is undoubtedly a very useful tool that can be utilized to prevent drug diversion and doctor shopping.

Since its authorization by the DEA, the EPCS rate of adoption on the state level has increased dramatically. Pharmacists have adopted EPCS at a rate of 78 percent, but providers who have concerns about implementation costs and complexity have only adopted EPCS at a rate of approximately 2 percent. It is incumbent upon state health leaders and private industry to partner with the medical community to advocate the many benefits of EPCS and its ability to easily integrate into and operate with their existing records systems.

HID Global and its identity assurance solutions provide the "gold standard" for defining, issuing and managing trusted identities on a global basis. DEA regulations require identity proofing and the issuance of Digital Certificate Tokens which are used to digitally sign and electronically send prescriptions for controlled substances. By providing the required information to a certificate authority, such as IHID Global, prescribers and pharmacists have the ability and confidence to seamlessly authenticate communication with a high degree of certainty. HID Global is the first certified issuer of Access Certificates for Electronic Services (ACES) and has issued ACES certificates for more than 10 years. The purpose of ACES is to facilitate public access to the services offered by government agencies through the use of online technologies, for purposes of reviewing, retrieving, providing, and exchanging information.

EPCS-THE PROCESS

A healthcare practitioner accesses their Electronic Healthcare Record (EHR) application that includes a prescribing function.

Step 1- An agent may prepare the prescription for review and signature by the DEA authorized practitioner

Step 2- Practitioner accesses list of prescriptions for a single patient which displays:

- Date of issuance
- Patient name
- Drug name, strength, form, quantity prescribed, directions for use
- Name, address, DEA registration number of practitioner
- Other information as applicable
- Onscreen statement that completion of two-factor authentication protocol is legally signing prescription(s) and authorizing transmission to pharmacy for dispensing

Step 3- Practitioner indicates the prescription(s) are ready to be digitally signed

- Multiple prescriptions for a single individual may be signed

Step 4 - Practitioner prompted to complete two-factor authentication protocol

- Practitioner acknowledges he/she is digitally signing the prescription
- For One Time Passcode/word (OTP), practitioner is authenticated via OTP. Once authenticated, the application digitally signs DEA elements with a server certificate, sets signature indicate (SI) flag, and transmits message.
- For certificate on hardware, digital signing requires the practitioner to authenticate to the hardware device, accomplishing two-factor authentication. The digitally signed message is transmitted.
- The application archives the digitally signed EPCS message

Regardless of whether signing with a server or practitioner certificate, the application must be enabled to digitally sign the required EPCS elements and then archive it.

IdenTrust
HealthCare

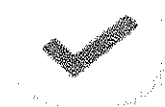
Easy 4 Step Plan

1



**EHR Software
Readiness**

2



**Identity
Proofing**

3



**Two-Factor
Authentication**

4



**Configuring
Access**

LEGISLATIVE EFFORTS

In 2013, the New York State Legislature passed the Internet System for Tracking Over-Prescribing - Prescription Monitoring Program, or I-STOP program. While it has been in effect since August 2013, New York Governor Cuomo and the Legislature amended the law in 2015 to allow for an extension of the mandate's effective date. This extension was mainly to allow providers and pharmacies the time necessary to comply with the law. As of March 27, 2016, the I-STOP program has been in full effect, and the technology industry has been actively engaging both providers and pharmacists to help educate on how to deploy an EPCS system.

Since the New York mandated extension to March 27, 2016, results of the I-STOP program have yet to be quantified. However, most providers and pharmacists have taken the necessary steps to comply. To date, New York leads the US with the highest percentage of providers able to prescribe controlled substances electronically. The private sector will continue to partner with providers and pharmacists to ensure that compliance occurs as seamlessly as possible.

In Louisiana, Representative Hunter proposed HB 1054 to mandate EPCS of Schedule II drugs (Opioid prescription drugs fall under the Schedule II distinction). Massachusetts also has similar legislation filed this session that mandates EPCS. Additionally, Florida, Maine and Rhode Island legislators filed legislation that would explicitly allow EPCS for controlled substances. The National Association of State Controlled Substances Authorities, whose membership includes a representative from every state, adopted a resolution in 2015 advocating state agency officials and policymakers to adopt legislation to require an EPCS system in compliance with the DEA's rule.

It should be noted that Minnesota requires their doctors to electronically prescribe, but does not penalize for non-compliance. However, as of 2014, electronic prescriptions have become a common practice in the State. Ninety-five percent of dispensers, 94 percent of clinics, and 65 percent of hospitals are regularly e-prescribing non-controlled substances.

CONCLUSION

Prescription drug abuse has destroyed communities, shattered families and cost millions in incarceration and medical expenses. The commitment to finding long term solutions cannot occur in silos. Rather, each entity and institution that is affected must come together to determine a holistic approach that incorporates the experience from those struggling with this crisis on the front lines, as well as access the resources and expertise available from the private sector. A solution such as electronic prescribing is simply one tool available to address the crisis, and HID Global stands ready to partner with the state of Michigan to serve as a trusted advisor to advocate the benefits of EPCS.